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EMD or subepithelial connective tissue graft for the treatment of single gingival recessions: a pilot study

E. A. Alkan[1], A. Parlar[2]*
[1]Department of Periodontology, Faculty of Dentistry, Yuzuncu Yil University, Van, Turkey and [2]Department of Periodontology, Faculty of Dentistry, Gazi University, Ankara, Turkey

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Background and Objective: The combination of EMD with root-coverage procedures has been shown to promote periodontal regeneration on the exposed root surface. The aim of this randomized clinical study was to compare the efficacy of EMD with connective tissue graft (CTG) for the treatment of Miller Class I and Class II single recessions in a split-mouth design.

Material and methods: The study included 12 systemically healthy patients, each with two single bilateral gingival recession defects (24 recessions). One recession defect in each patient was treated with the coronally advanced flap (CAF) + EMD procedure and the other recession defect was treated with the CTG + EMD procedure, in a split-mouth study design. The parameters recession depth (RD), recession width, percentage of root coverage, height of keratinized tissue (HKT), gingival thickness, probing depth and clinical attachment level (CAL) were recorded at baseline. All parameters, except for gingival thickness, were remeasured at 6 and 12 mo.

Results: The mean percentage root coverage at the final evaluation was 92 ± 14% for the CAF + EMD group and 89 ± 14% for the CAF + CTG group. Both treatments resulted in statistically significant ($p < 0.05$) decreases in RD and recession width, and increases in HKT, at 6 and 12 mo. There was also a significant decrease in the probing depth and a significant gain in the CAL for both groups. The probing depth was statistically higher in the CAF + CTG group than in the CAF + EMD group at 6 mo ($p < 0.05$), while the CAL was statistically lower in the CAF + EMD group than in the CAF + CTG group at 6 and 12 mo ($p < 0.05$).

Conclusion: The present study demonstrated that both CAF + EMD and CAF + CTG procedures were similarly successful in treating Miller Class I and Class II single gingival recession defects.

Eylem A. Alkan, PhD, Department of Periodontology, Faculty of Dentistry, Yuzuncu Yil University, Van, Turkey
Tel: +90 505 7030341
Fax: +90 432 2251747
e-mail: eylemayhan79@yahoo.com

*Present address: Private Practice, Ankara, Turkey.

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Gingival recession is an apical shift of the gingival margin that results in exposure of the root surface to the oral cavity (1). Gingival recession is stratified into four classes, based on the prognosis of root coverage. In Class I and Class II, there is no loss of interproximal periodontal attachment and bone. In Class III, the loss of

interproximal periodontal support is mild to moderate, and in Class IV, the loss of interproximal periodontal attachment is severe (2). Indications for root coverage include root sensitivity, esthetic demand and the prevention of root caries (3,4). Various surgical approaches are commonly used for this purpose, such as pedicle flaps, free gingival grafts and regeneration with the use of barrier membranes. Among these techniques, the subepithelial connective tissue graft (CTG) procedure is conventionally and widely performed and seems to be the gold standard because of its favorable outcomes for root coverage (2,5–7). Nevertheless, graft removal from the palate has possible complications.

The coronally advanced flap (CAF) technique is a simple procedure that does not require a second surgical site (8). Many studies have evaluated the addition of different materials placed under the CAF to improve root coverage. Recently, gingival recession defects treated with EMD (9–12) were compared to gingival recession defects treated with conventional surgical techniques, with the goal of periodontal regeneration, which resulted in the formation of long junctional epithelium (8,11). EMD is an amelogenin derivative, obtained from porcine embryogenesis, that is thought to mimic the role of enamel matrix proteins in cementogenesis during nascent root development (10,13). It was found that the use of EMD resulted in periodontal regeneration when applied to a denuded root surface (9,10,13–15). Heijl (13) reported new cementum and bone gain, as measured histologically, in one experimentally created recession defect. McGuire and Cochran (15) reported no histological evidence of cementum, bone or periodontal ligament regeneration in the CTG group; and the authors also reported the formation of new cementum, periodontal ligament fibers and islands of condensing bone at a constant distance from the root surface in the EMD group.

Clinical studies have shown the possibility of combining EMD with root-coverage procedures, especially CAF procedures, to achieve root coverage and periodontal regeneration on the root surface (13,14). EMD associated with CTG showed significantly better results in recession depth (RD), clinical attachment level (CAL) and probing depth parameters compared with CTG alone in Miller Class III recession defects (16). Sculean *et al.* (17) reported better long-term results following CAF procedures with the addition of EMD than those using a similar procedure without EMD. Nevertheless, some studies (9,18) questioned the benefit of using EMD with CAF because no significant difference was found between EMD + CAF and CAF-only groups. Nemkovsky *et al.* (7) found that the CTG procedure was superior to EMD in terms of the percentage of coverage and increase in keratinized tissue. There are conflicting results about the clinical benefits of EMD, and limited studies are available to indicate that the use of EMD could be an alternative treatment to CTG.

Based on these reports, the purpose of this randomized clinical study was to compare the efficacy of EMD with the CTG procedure for the treatment of Miller Class I and Class II single recession defects in a split-mouth design.

Material and methods

Patient selection and experimental design

The study employed a split-mouth design that included 12 systemically healthy nonsmoking patients (seven female and five male), who were between 23 and 42 years of age and had two similar single bilateral Miller Class I and Class II recession defects (≥ 2 mm) in canines or premolars. The patients were not taking any medication and had no history of previous periodontal plastic surgery. The selected teeth had vital pulp and were free from caries and restorations. Periapical radiographs were taken to evaluate the interproximal alveolar bone level. Initially, a hygiene phase, and scaling and polishing, were performed; the teeth were then re-evaluated 3 mo later. Each patient was treated on one site with CAF + EMD (Fig. 1) and on the other site with CAF + CTG (Fig. 2). The treatment procedure (CAF + EMD or CAF + CTG) at each site was determined by the toss of a coin. The Institutional Review Board at Gazi University, School of Medicine, approved the study protocol, and our protocol number for ethical approval was 422. All subjects received a detailed explanation of the procedures and objectives of the study and gave informed consent before participating in the study.

Surgical procedures

The surgical procedure was similar at both sites. After local anesthesia, root debridement was performed to provide a flattened surface. An intrasulcular incision was made with a no. 15 C blade on the buccal aspect of the involved tooth. Two horizontal incisions were made from the mesial and distal angles of the tooth to the papillae without involving the gingival margin of the adjacent teeth. Two oblique releasing incisions were made from the mesial and distal extremities of the intrasulcular buccal incisions beyond the mucogingival junction. The full-thickness trapezoidal flap was raised with a periosteal elevator toward the mucogingival junction, and then a partial-thickness dissection was performed apically towards the marginal bone crest. The papillae adjacent to the involved teeth were de-epithelialized, and the root surface was conditioned with 24% EDTA gel (Straumann PrefGel; Straumann, Basel, Switzerland) for 2 min to remove the smear layer and then rinsed with sterile saline solution to remove all EDTA residues.

CAF + EMD-treated sites— Before application, EMD (Straumann Biologics Division, Waltham, MA, USA) which was stored in a refrigerator at 2–8°C was warmed at room temperature for 15 min. EMD was then applied to the entire root surface, starting from the most apical bone level. Sling sutures then provided a precise adaptation of the buccal flap on the exposed root surfaces. Interrupted sutures were utilized to attach the base of the trapezoidal flap to the neighboring soft

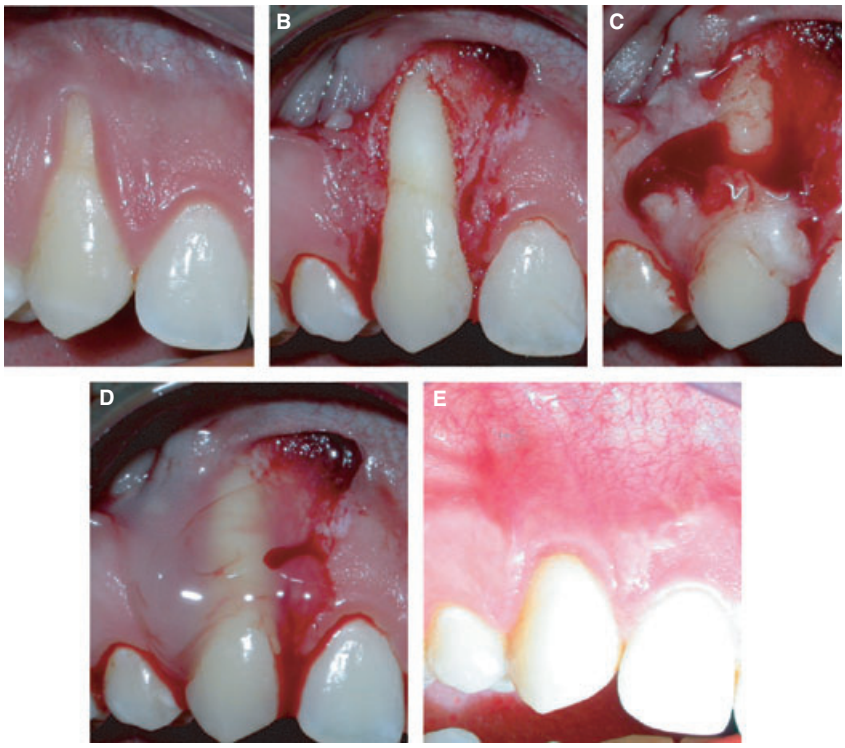

Fig. 1. Clinical aspect of a site treated by the coronally advanced flap (CAF) + EMD procedure. (A) Preoperative view of a maxillary right canine. (B) Intra-operative view of a denuded root surface. (C) EDTA application for root conditioning. (D) EMD application. (E) 12 mo after surgery.

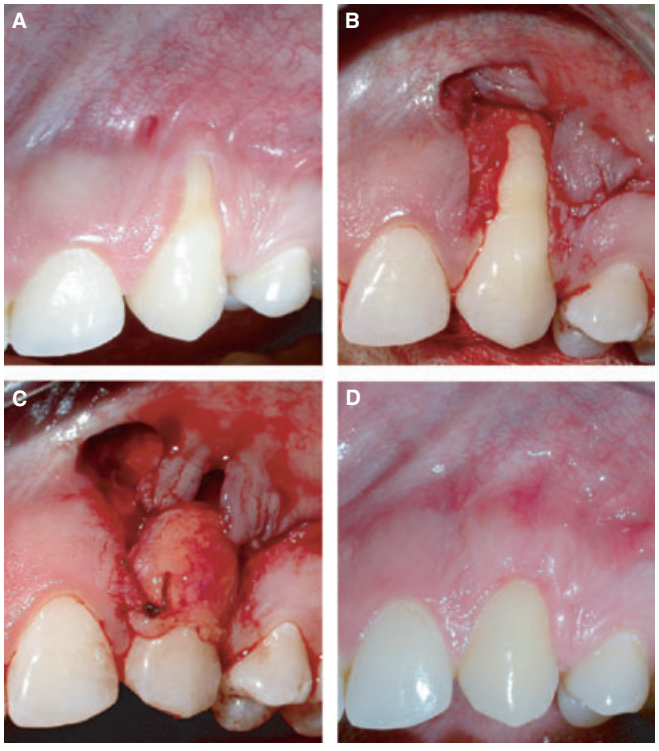

Fig. 2. Clinical aspect of a site treated by the coronally advanced flap + connective tissue graft (CAF + CTG) procedure. (A) Preoperative view of a maxillary left canine. (B) Intra-operative view of a denuded root surface. (C) CTG adaptation. (D) 12 mo after surgery.

tissues; 5–0 silk suture was used. After suturing, EMD was placed on the root surface underneath the advanced flap by introducing the syringe needle between sutures through the oblique incisions.

CAF + CTG-treated sites— A connective tissue graft was obtained from the palate and fixed with a sling suture to the neck of the tooth using bioabsorbable suture. The pedicle flap was sutured over the connective tissue graft, with some coronal repositioning using sling suture.

Postoperative care— Patients were instructed not to brush their teeth in the treated area but to rinse their mouth with chlorhexidine solution (0.12%) twice daily; analgesics were prescribed, if necessary. Two weeks after the surgical treatment, the sutures were removed. Plaque control in the surgically treated area was maintained by chlorhexidine rinsing for an additional 2 wk. After 2 wk, the patients were again instructed in mechanical tooth cleaning. Patients were recalled 1, 3 and 5 wk after suture removal and then once every 3 mo until the end of the study. If necessary, professional supragingival tooth cleaning was performed during follow-up visits.

Clinical measurements

All measurements were collected by a single calibrated investigator using a Michigan periodontal probe and were recorded to the nearest millimeter. The full-mouth plaque index (19) and full-mouth gingival index (20) were recorded to assess the gingival health throughout the study. The clinical parameters described in the following paragraph were measured at the facial aspect of the experimental teeth.

Gingival RD, was measured from the cemento–enamel junction to the most apical extension of the gingival margin. Gingival recession width was measured at the level of the cemento–enamel junction. Probing depth was measured from the gingival margin to the bottom of the gingival sulcus. Clinical attachment level (CAL) was measured from the cemento–enamel

junction to the bottom of the gingival sulcus. The percentage of root coverage of the original defect was calculated using the formula:

$$\left(\frac{\mathrm{RD(baseline)} - \mathrm{RD(post\text{-}op)}}{\mathrm{RD(baseline)}}\right) \times 100$$

The height of keratinized tissue (HKT) was measured from the gingival margin to the mucogingival junction. Gingival thickness (GT) was measured at a midbuccal location, 3 mm below the gingival margin, using an endodontic spreader with a silicone disk stopper inserted in a perpendicular manner into the gingival tissue. The penetration depth was measured using a caliper with a 0.01-mm resolution. The clinical measurements of the HKT and the GT were performed three times, and the mean of these three values was used to represent the HKT and the GT (21). All measurements, except the GT, were repeated at 6 and 12 mo postsurgery.

Statistical analysis

Statistical analysis was performed using a statistical software package (SPSS statistical package version 13.0; SPSS, Inc., Chicago, IL, USA). The differences between the baseline clinical parameters and those at the 6- and 12-month follow-up examinations were evaluated using the Friedman test. The Wilcoxon signed-rank test was used to determine whether the differences between the CAF + EMD and CAF + CTG groups were statistically significant. A $p < 0.05$ was considered as statistically significant. A statistical power analysis was performed using percentage of root coverage as the primary outcome variable. We had 8% power at 6 mo and 11% power at 12 mo.

Results

Postoperative healing at all sites, including palatal donor sites, was uneventful for all patients. Full-mouth gingival index and plaque index were maintained below 20%. The target teeth were free of plaque and gingival inflammation before periodontal surgery and at the end of the study. The statistical analyses for the clinical parameters at baseline and postsurgery for the CAF + EMD and CAF + CTG groups are shown in Table 1. The baseline clinical parameters in both groups were not statistically significant, but both treatments resulted in statistically significant (all $p < 0.05$) decreases in RD and recession width, and increases in HKT, at 6 and 12 mo postsurgery. However, no difference was noted between the two groups. The mean percentage root coverage at the final evaluation was 92 ± 14% for the CAF + EMD group and 89 ± 14% for the CAF + CTG group. Complete root coverage was achieved at 12 mo in nine of the 12 patients in the CAF + EMD group and in seven of the 12 patients in the CAF + CTG group. There was also a significant decrease in the probing depth and a significant gain in the CAL for both groups. The probing depth was statistically higher in the CAF + CTG group than in the CAF + EMD group at 6 mo ($p < 0.05$), while the CAL was statistically lower in the CAF + EMD group than in the CAF + CTG group at 6 and 12 mo ($p < 0.05$).

Discussion

The aim of this prospective, randomized, split-mouth clinical study was to evaluate the ability of EMD to improve root coverage in single Miller Class I and Class II recession defects compared with the subepithelial CTG. The results showed that both treatments produce significant improvements in clinical parameters. Both surgical approaches were highly effective in obtaining root coverage and esthetic improvements, in agreement with previous clinical studies (12,22,23). The addition of CTG or EMD is thought to enhance the clinical outcomes of CAF in terms of root coverage. Cairo *et al.* (24) reported that no treatment, except for EMD + CAF, matched the effectiveness of CTG + CAF in terms of complete root coverage. The difference in the CAL observed between the groups at 6 and 12 mo after surgery could be partly caused by the regenerative potential of EMD. In many other studies, EMD (22,25–28) and CTG (29,30) cause a significant reduction in the gain of probing depth and of CAL. According to our results, the probing depth showed a statistically significant decrease after treatment in both groups, but it was statistically higher in the CAF + CTG group than in the CAF + EMD group at 6 mo; this result suggests that root coverage by the CAF + EMD procedure does not result in pocket formation during contrast tissue attachment on the exposed root surface.

The increase in the HKT after the CAF + CTG (4,22,31) and CAF + EMD (11,12,18,22) procedures has been widely demonstrated in previous studies. Almost no change in the HKT was observed when the same procedure was performed without the addition of EMD (18). In our study, there was a significant increase in the HKT in both groups from baseline to 12 mo. The application of EMD may act as a barrier to permit granulation tissue, growing from the periodontal ligament surrounding the recession, to repopulate the exposed root surface under the protection of the CAF (12). The increase of connective tissue in the CAF + CTG group was explained by the established concept that the information in the connective tissue ultimately determines the character of the surface epithelium. In the study by Karring *et al.* (32), the CTG that originated from keratinized gingiva was placed onto nonkeratinized alveolar mucosa, which subsequently gained keratinized features of the gingiva.

A specific thickness of the GT associated with a complete root-coverage procedure (33). Moriyama *et al.* (34) reported that a flap thickness of ≥ 1 mm was associated with 100% root coverage. In the present study, the baseline GT was not significantly different between groups, so there was homogeneity of the experimental sites at the start of the study.

Cairo *et al.* (24) explained the difference between the indications of CAF + EMD and CTG + EMD as follows: CAF + EMD should be used when connective tissue cannot be harvested and a sufficient flap can be moved to the coronal side; CTG +

Table 1. Clinical parameters (mean ± SD) at baseline, and at 6 and 12 mo postoperatively

	CAF + EMD				CAF + CTG			
Clinical parameters	Median	Mean ± SD	Minimum	Maximum	Median	Mean ± SD	Minimum	Maximum
RD								
Baseline	3.00	3.50 ± 1.00b	2.00	6.00	3.00	3.58 ± 0.79b	3.00	5.00
6 mo	0.00	0.33 ± 0.49a	0.00	1.00	0.00	0.42 ± 0.51a	0.00	1.00
12 mo	0.00	0.33 ± 0.65a	0.00	2.00	0.00	0.42 ± 0.51a	0.00	1.00
Difference (0–6 mo)	3.00	3.17 ± 0.94	2.00	5.00	3.00	3.17 ± 0.83	2.00	5.00
Difference (0–12 mo)	3.00	3.17 ± 0.72	2.00	4.00	3.00	3.17 ± 0.83	2.00	5.00
Difference (6–12 mo)	0.00	0.00 ± 0.43	−1.00	1.00	0.00	0.00 ± 0.43	−1.00	1.00
RW								
Baseline	3.00	3.08 ± 0.79b	2.00	4.00	3.00	2.83 ± 0.83b	2.00	4.00
6 mo	0.00	0.00 ± 0.00a	0.00	0.00	0.00	0.42 ± 0.51a	0.00	1.00
12 mo	0.00	0.08 ± 0.29a	0.00	1.00	0.00	0.50 ± 0.67a	0.00	2.00
Difference (0–6 mo)	3.00	3.08 ± 0.79	2.00	4.00	2.50	2.42 ± 1.08	1.00	4.00
Difference (0–12 mo)	3.00	3.00 ± 0.85	2.00	4.00	2.00	2.33 ± 1.07	1.00	4.00
Difference (6–12 mo)	0.00	−0.08 ± 0.29	−1.00	0.00	0.00	−0.08 ± 0.51	−1.00	1.00
HKT								
Baseline	2.00	2.42 ± 0.79b	1.00	4.00	2.00	2.17 ± 1.03b	1.00	4.00
6 mo	5.00	4.83 ± 1.53a	3.00	7.00	4.50	4.58 ± 1.62a	2.00	8.00
12 mo	5.00	5.08 ± 1.51a	3.00	8.00	4.50	4.58 ± 1.38a	2.00	7.00
Difference (0–6 mo)	−3.00	−2.42 ± 1.56	−5.00	0.00	−3.00	−2.42 ± 1.68	−5.00	0.00
Difference (0–12 mo)	−3.00	−2.67 ± 1.37	−4.00	0.00	−3.00	−2.42 ± 1.44	−4.00	0.00
Difference (6–12 mo)	0.00	−0.25 ± 0.62	−1.00	1.00	0.00	0.00 ± 0.43	−1.00	1.00
PD								
Baseline	1.50	1.54 ± 0.37a	1.00	2.00	1.50	1.50 ± 0.35a	1.00	2.00
6 mo	1.00	1.04 ± 0.10b	1.00	1.25	1.25	1.29 ± 0.26b*	1.00	1.75
12 mo	1.00	1.02 ± 0.07b	1.00	1.25	1.13	1.13 ± 0.13b	1.00	1.25
Difference (0–6 mo)	0.50	0.50 ± 0.37	0.00	1.00	0.13	0.21 ± 0.26	0.00	0.75
Difference (0–12 mo)	0.50	0.52 ± 0.38	0.00	1.00	0.38	0.38 ± 0.29	0.00	0.75
Difference (6–12 mo)	0.00	0.02 ± 0.07	0.00	0.25	0.00	0.17 ± 0.22	0.00	0.50
CAL								
Baseline	4.63	5.04 ± 0.64a	2.75	6.00	4.75	5.08 ± 0.48a	3.00	6.00
6 mo	1.13	1.37 ± 0.27b	1.00	2.00	1.50	1.71 ± 0.41b*	1.00	2.75
12 mo	1.12	1.35 ± 0.48b	1.00	3.00	1.35	1.55 ± 0.28b*	1.00	2.25
Difference (0–6 mo)	3.38	3.67 ± 0.72	1.50	5.00	3.00	3.37 ± 0.44	1.25	4.25
Difference (0–12 mo)	3.38	3.69 ± 0.68	1.75	5.00	3.25	3.53 ± 0.38	1.75	4.00
Difference (6–12 mo)	0.00	−0.02 ± 0.33	−1.00	0.25	0.25	0.16 ± 0.44	−1.00	0.75
PRC								
6 mo (%)	100	91 ± 14a	67	100	100	89 ± 14a	67	100
12 mo (%)	100	92 ± 14a	67	100	100	89 ± 14a	67	100
Difference (6–12 mo)	0.00	−0.01 ± 0.11	−0.33	0.16	0.00	0.00 ± 0.09	−0.20	0.20
GT								
Baseline	1.00	1.00 ± 0.18	0.70	1.30	1.00	1.04 ± 0.14	0.80	1.30

Different letters (a, b) indicate a statistically significant difference among experimental periods within the same group ($p < 0.05$).
*Statistically significant difference between-group comparison ($p < 0.05$).
CAF, coronally advanced flap; CAL, clinical attachment level; CTG, connective tissue graft; GT, gingival thickness; HKT, height of keratinized tissue; PD, probing depth; PRC, percentage of root coverage; RD, recession depth; RW, recession width.

EMD should be used when the flap to cover the root surface is thin and a sufficient size of flap cannot be moved to the coronal side.

One limitation of our study was the small number of subjects. A statistical power analysis was performed using percentage of root coverage as the primary outcome variable. We had 8% power at 6 mo and 11% power at 12 mo. Expanded split-mouth studies are needed to support our results. Another limitation of our study was that it is impossible to assess the nature of attachment only by clinical examination.

Conclusion

The present study demonstrates that both CAF + EMD and CAF + CTG procedures were similarly successful in treating Miller Class I and Class II single gingival recession defects. Our results, taken together with the results

reported from previous clinical studies, suggest that CAF + EMD is an effective treatment alternative to achieve root coverage.

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